UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
NORTHEASTERN DIVISION

DAVID HALSTEAD,	)
	)
Plaintiff,	) **CIVIL ACTION NO.: _____**
v.	)
	)
ZIMMER US, INC.;	) **JURY TRIAL DEMANDED**
ZIMMER HOLDINGS, INC.,	)
ZIMMER, INC., AND ZIMMER	)
SURGICAL, INC.	)
	)
Defendants.	)
_____	)

COMPLAINT

Plaintiff, David Halstead, by and through his attorneys, respectfully submits the following Complaint and Jury Demand against Defendants Zimmer U.S., Inc., Zimmer Holdings, Inc., Zimmer, Inc. and Zimmer Surgical, Inc. (collectively referred to as "Zimmer" or "Defendants"), and alleges the following:

NATURE OF THE ACTION

1. This is an action for strict products liability, failure to warn, defective design, negligence, breach of express and implied warranties, negligent misrepresentation and punitive damages brought by Plaintiff, David Halstead, for injuries arising out of the Zimmer M/L Taper® Hip System.

2. Defendant Zimmer manufactured and supplied to doctors total hip arthroplasty system known as the Zimmer M/L Taper® Hip System, which was designed

to be implanted with either (1) a cobalt-chromium femoral head or (2) a ceramic femoral head.

3. The Zimmer M/L Taper® Hip System utilized with cobalt-chromium femoral head created unreasonable risks of harm to Plaintiff.

4. The unreasonable risks of pain, swelling, metallosis, trunnionosis, adverse local tissue reaction, and/or the need for early revision surgical intervention, whether from corrosion, micromotion, fretting or some other mechanism, renders the Zimmer M/L Taper® Hip System with a metal cobalt-chromium femoral head a defective product.

5. The selection and implantation of the Zimmer M/L Taper® Hip System by Plaintiff's surgeon, John Martino, M.D., was a result of the misinformation, marketing, sales, promotion and direction by Zimmer.

6. As a result of these and other defects, which are described in greater detail below, Plaintiff's Zimmer M/L Taper® Hip System had an unreasonably high risk of failing in his body, causing toxic levels of cobalt and chromium debris, tissue and bone destruction, and the need for Plaintiff to undergo a complicated and risky surgery to remove and replace the defective implant. Plaintiff underwent this revision surgery on or about March 11, 2021, at Carilion Roanoke Memorial Hospital in Roanoke, Virginia.

JURISDICTION & VENUE

7. This is a lawsuit over defective hip implant components designed, marketed, manufactured, promoted and sold by Defendants Zimmer U.S., Inc., and Zimmer Holdings, Inc., Zimmer, Inc., and Zimmer Surgical, Inc. of which U.S. District Court for the Eastern District of Tennessee has original jurisdiction under 28 U.S.C. section 1332 because it is

between citizens of different states (as described below) and the amount in controversy exceeds the sum or value of $75,000, exclusive of costs and interest.

8. Plaintiff, David Halstead, is and was at all times relevant, a citizen and resident of Blountville, Sullivan County, Tennessee, at the time the Zimmer M/L Taper Hip System manufactured, designed, distributed, and warranted by Defendants was implanted into Plaintiff. Plaintiff's surgeon, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hip replacement surgery.

9. Defendant ZIMMER US, INC. was registered as a Delaware Corporation and was duly registered and/or licensed to do business in the state of Tennessee. Zimmer U.S., Inc.'s registered agent in Tennessee is Corporation Service Company, 2909 Poston Ave., Nashville, Tennessee 37203-1312.

10. At all relevant times, ZIMMER HOLDINGS, INC. was registered as a Delaware Corporation and is a corporation organized and existing under the laws of Delaware and has a principal place of business located in Warsaw, Indiana. Zimmer Holdings, Inc.'s registered agent in Indiana is Corporation Service Company located at 251 E. Ohio St., Suite 500, Indianapolis, Indiana 46204.

11. ZIMMER HOLDINGS, INC. is a publicly traded for-profit parent corporation that, through its subsidiaries, engages in the design, development, manufacture, and marketing of orthopedic reconstructive implants, spinal and trauma devices, dental implants, and related surgical products. Zimmer Holdings, Inc. was founded in 1927.

12. At all relevant times, ZIMMER, INC. was registered as a Delaware Corporation and is a wholly owned subsidiary of Zimmer Holdings, Inc., and is organized and existing under the laws of Delaware, with its principal place of business located in Warsaw, Indiana.

13. Zimmer, Inc. engages in the design, research, development, manufacture, and marketing of orthopedic reconstructive implants and related surgical products, including the Zimmer Device that is the subject of this lawsuit.

14. At all relevant times, ZIMMER SURGICAL, INC. was registered as a Delaware corporation with its registered agent in Indiana: Corporation Service Company located at 251 E. Ohio Street, Suite 500, Indianapolis, Indiana 46204.

15. The Defendants are subject to jurisdiction within the state of Tennessee and this Court because:

a. The Defendants are engaged in substantial and not isolated business activity within the state of Tennessee, Sullivan County;

b. The Defendants' products, including the subject Zimmer M/L Taper Hip System, which they designed and manufactured, were placed into the stream of commerce by the Defendants and were used within the state of Tennessee in the ordinary course of commerce, trade or use;

c. The subject Zimmer M/L Taper Hip System caused injury to persons, including Plaintiff, David Halstead, within the state of Tennessee as a result of the tortious and wrongful acts and omissions of the Defendants as set forth more fully herein;

d. The Defendants maintain an office or agency within the state of Tennessee; and

e. Upon information and belief, at all relevant times, Defendants committed tortious act(s) within the state of Tennessee out of which act(s) these causes of action arise.

16. At all times relevant hereto, the Defendants developed, manufactured, advertised, promoted, marketed, sold and/or distributed the defective Zimmer M/L Taper Hip System, throughout the United States, including within the state of Tennessee and specifically to Plaintiff David Halstead's implanting physician or his practice group, or to the hospital where the Zimmer M/L Taper Hip System was implanted.

GENERAL FACTUAL ALLEGATIONS

17. Defendants were the designers, manufacturers, and suppliers of the Zimmer M/L Taper® Hip System and related components in the business of putting medical devices on the market.

18. Zimmer warranted the Zimmer M/L Taper® Hip System and placed the device into the United States stream of commerce.

19. Before it set out to design the Zimmer M/L Taper® Hip System, Zimmer knew of the danger to human beings if cobalt-chromium metal debris from its products were released into the body through corrosion, micromotion, and/or fretting.

20. Before placing the Zimmer M/L Taper® Hip System on the market, Zimmer was required to mitigate risks of the product, including any element of the design that created toxic levels of corrosion and debris that could result in pain, swelling, pseudotumor formation, osteolysis, instability, dislocation, metallosis, trunnionosis, adverse tissue reaction and/or the need for early surgical revision in patients-consumers.

21. The Zimmer M/L Taper® Hip System taper is a 12/14 size with threading on the taper. This threading can be described as shallow grooves on the portion of the taper that articulates with the head. This threading on the taper is used to comply with the requirements of the manufacturer of ceramic head option, CeramTec.

22. The significance of the Zimmer M/L Taper® Hip System taper threading is (1) it protects ceramic heads and (2) provides an interface at the junction with a metal head which is much more likely to produce wear and debris under fretting conditions. The threads were not designed to enhance the performance of metal heads.

23. The decision to allow the use of metals and CoCr heads (rather than ceramic heads) in the Zimmer M/L Taper® Hip System created an unreasonable risk and made it defective.

24. The concept that corrosion might occur at the head-neck taper junction of a total hip prosthesis was first described in the early 1980s. When Zimmer was designing the Zimmer M/L Taper® Hip System this concept had to be a consideration.

ZIMMER M/L TAPER® HIP SYSTEM

25. The Zimmer M/L Taper® Hip System implanted into Plaintiff David Halstead's right hip primarily consisted of four component parts: (a) the M/L Taper® Femoral Stem which was made of titanium alloy, (b) the Versys® Hip System Femoral Head which was made of cobalt/chromium alloy which was affixed to the trunnion of the femoral stem, (c) the Converge Acetabular System Shell which was made of titanium alloy, and (d) the Epsilon Durasul® Liner which was made of highly cross-linked polyethylene.

Plaintiff's Zimmer M/L Taper® Hip System is referred to as a "metal-on-polyethylene" bearing system.

26. In designing the Zimmer M/L Taper® Hip System, Zimmer knew that the use of dissimilar metal alloys as well as taper size and geometry, trunnion surface finish, and flexural rigidity contribute to causing fretting and corrosion at the femoral head-neck /stem taper interface.

27. Mechanically assisted crevice corrosion ("MACC") has been identified as a cause for symptomatic implant failure in metal-on-polyethylene hip devices. MACC produces cobalt and chromium ions, fretting byproducts and corrosive debris that can lead to adverse local tissue reaction.

28. Adverse local tissue reaction, also referred to as aseptic lymphocyte dominated vasculitis-associated lesions ("ALVAL"), represents a distinctive periprosthetic inflammatory reaction accompanied by extensive necrosis in the soft tissue-envelope of the hip. Early detection of adverse local tissue reaction is important because as time from onset of MACC to revision surgery increases, tissue damage may worsen.

FAILURE TO WARN PHYSICIANS OF THE DANGERS ASSOCIATED WITH THE ZIMMER M/L TAPER® HIP SYSTEM

29. Zimmer marketed its hip implants, including the Zimmer M/L Taper® Hip System, to orthopedic surgeons and hospitals rather than end-user patients.

30. Zimmer had the ability to inform surgeons or hospitals of developing problems or defects in its devices through e-mail, letter, recalls, warnings in product inserts and/or through its product representative(s), who works directly with the surgeon.

31. The mechanical environment of the junction place the Zimmer M/L Taper® Hip System at increased risk for failure from pain, swelling, pseudotumor formation, metallosis, adverse local tissue reaction, synovitis, osteolysis, and/or dislocation, resulting from excessive wear debris, fretting corrosion and recurrent repassivation.

32. The fretting process (mechanical micromotion) is strongly influenced by distribution of pressure and force at the junctions, rendering these junctions vulnerable to accelerated generation of metal wear debris and corrosion.

33. Each interface introduces a contributing source for metal wear particular and debris generation. These junctions exponentially compound and accelerate the wear debris generation process.

34. Corrosion is time-sensitive and accelerated with mechanical stresses. This phenomenon was known to Zimmer, or should have been known by Zimmer, at all times relevant to the design, manufacture, marketing and sale of the Zimmer M/L Taper® Hip System.

35. At the time of design, manufacture, testing and marketing, Zimmer knew or should have known, combinations of metal alloys at a junction, such as the metal CoCr heads and cobalt-chromium and/or titanium neck/stem junctions of the Zimmer M/L Taper® Hip System, generate excessive fretting, corrosion, and metal wear debris.

36. Zimmer did not inform or warn and is still not informing or warning physicians or consumers either through its sales representatives, correspondence, advertising or package inserts that:

a. Selection of a metal CoCr head rather than a ceramic head to pair with the cobalt-chromium and/or titanium neck/stem significantly increases the risk of toxic amounts of corrosion and metal debris which might cause pain; swelling; metallosis; trunnionosis; tissue necrosis; adverse local tissue reaction; osteolysis; dislocation; and/or the need for early revision;

b. Upon information and belief, Zimmer's pre-market corrosion testing, if any, was inadequate as it pertains to the Zimmer M/L Taper® Hip System; and/or,

c. Upon information and belief, Zimmer's Spectrum Accelerated Corrosion Fatigue ("SACF") Testing, if any, was inadequate as it pertains to the Zimmer M/L Taper® Hip System.

37. Zimmer never performed any clinical trials and/or studies prior to marketing the Zimmer M/L Taper® Hip System.

38. Zimmer did not fully and/or adequately test the configuration utilizing CoCr femoral heads and cobalt-chromium and/or titanium neck/stem junctions that were implanted into Plaintiff.

39. Zimmer continues to market the CoCr heads for use with the cobaltchromium and/or titanium neck/stems in the Zimmer M/L Taper® Hip System.

40. Reassurances of device safety were made through direct promotional contact by Defendants' sales representatives and distributors, through word-of-mouth from Zimmer's physician/technical consultants, and/or through industry targeted promotional materials.

41. Despite these reassurances, the defective design and manufacture of the Zimmer M/L Taper® Hip System, with a CoCr femoral head, generates excessive fretting and corrosion occurring at the head-neck/stem taper junctions. The fretting and corrosion

generate toxic metal debris, metal ions and other chemical byproducts which are released into the surrounding tissues. These metal debris, metal ions and byproducts destroy the surrounding tissue and bone, often causing pseudotumor and other metal related conditions. The release of metal debris and metal ions also causes systemic exposure to the toxic metallic elements, often reflected in elevated blood serum and/or urine testing levels.

42. Defendants were aware of the problems at the time that they designed, manufactured, marketed, distributed, and/or sold the Zimmer M/L Taper® Hip System. Nonetheless, Defendants employed the design in the Zimmer M/L Taper® Hip System in reckless disregard for the safety of patients, including Plaintiff.

43. Moreover, despite direct knowledge of significant adverse events reported by patients and physicians, as well as awareness of failures that have been reported in the literature and published in national registries, Defendants have continued to market the Zimmer M/L Taper® Hip System as being safe and effective with the CoCr femoral head.

44. From the time that Defendants first began selling the Zimmer M/L Taper® Hip System in the United States through today, its product labeling and product information failed to contain adequate information, instructions, and warnings concerning implantation of the product, specifically with the use of a CoCr femoral head, and its increased risks of fretting and corrosion.

45. The problems with the Zimmer M/L Taper® Hip System are similar in nature to the issues that gave rise to Stryker Orthopedics' recent recall of the LFIT® Anatomic CoCr V40 Femoral Heads and the Versys Femoral Heads are made of cobalt-chromium and both are mated with metal alloy stems. Stryker's Urgent Medical Device Recall

Notification states that the company initiated the worldwide recall after receiving higher than expected complaints of "taper lock failure" which could result in numerous potential hazards, including, but not limited to, excessive metal debris, excessive wear debris, disassociation of the femoral head from the hip stem and fractured hip stem trunnion leading to adverse local tissue reaction, implant loosening, loss of mobility, and pain requiring revision surgery.

PLAINTIFF'S USE OF THE PRODUCT

46. On January 8, 2013 a defectively designed, manufactured and marketed Zimmer M/L Taper® Hip System left the hands of Defendants in its defective condition, delivered into the stream of commerce, and was implanted in Plaintiff David Halstead's right hip at Wellmont Bristol Regional Hospital in Bristol, Tennessee by T. Lisle Whitman, M.D. Plaintiff was implanted on the right hip with the following components:

a. Versys® 12/14 Tapered Cobalt-Chromium femoral head;

b. M/L Taper® Femoral Stem 12/14 neck taper with standard neck offset;

c. Converge Acetabular System Cluster-Hole Porous Shell, 63 mm; and,

d. Epsilon Durasul Highly Cross-linked Polyethylene Acetabular Liner, 38 mm x 63mm.

47. As a direct and proximate result of Defendants' defective design, manufacture, marketing, distribution, and/or sale of the Zimmer M/L Taper® Hip System and placing the defective device into the stream of commerce, on January 8, 2013, Plaintiff underwent revision surgery at Wellmont Bristol Regional Medical Center in Bristol,

Tennessee, by T. Lisle Whitman, M.D. due to failed right total hip arthroplasty secondary to synovial metallosis, pseudotumor, and severe trunnionosis. Pain in the Plaintiff's hip and groin elevated and unsafe cobalt and chromium blood levels, trunnion corrosion and the presence of a pseudotumor and metal debris caused Plaintiff's surgeon to recommend the painful, costly and risky revision surgery. Intra-operative findings included cloudy fluid, a massive solid pseudotumor with necrosis, and grade two trunnion corrosion. A ceramic head was implanted.

48. The mechanism of failure in Plaintiff's devices was exactly the same as the mechanism of failure that Defendants had marketed and warranted would not occur because of the Zimmer M/L Taper® Hip System design and composition. It was also the same failure mechanism that the medical and scientific community had been studying and documenting in modular device designs since the 1990s.

49. Moreover, the symptoms and findings associated with modular device failures that have been reported in the literature are identical to those suffered by Plaintiff.

50. As a direct and proximate result of Defendant's defective design, manufacturing, marketing, distribution, sale and warnings, of the defective Zimmer M/L Taper® Hip System, Plaintiff has suffered and continues to suffer both injuries and damages, including, but not limited to: past, present and future physical and mental pain and suffering; physical disability, and past, present and future, medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.

THE FDA'S 510(k) CLEARANCE PROCESS

51. The 510(k) clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 (hereafter "MDA") of the Federal Food, Drug and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA approved for sale prior to 1976, when the MDA was enacted.

52. No clinical testing is required under this process.

53. Subsequent amendments to the MDA allowed for 510(k) clearance for products deemed "substantially equivalent" to post-MDA, 510(k) cleared devices.

54. Through the domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by the FDA prior to 1976 could be sold to patients in a matter of 90 days without any clinical testing.

55. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

56. In 2012, at the request of the FDA, the National Institute of Health (hereafter "NH") conducted a thorough review of the 510(k) process, coming to the following major conclusions:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

57. The NH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a "reasonable assurance of safety and effectiveness." Further, the NH even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . . Thus, is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

58. Zimmer cleared the M/L Taper® Hip System, and its related components, under a process used by the United States Food and Drug Administration known as the 510(k) Premarket Notification. Under Section 510(k) of the Federal Food, Drug and Cosmetic Act, a medical device does not have to go through the rigors of a clinical study to gain approval by the FDA. Instead, the device is supposed to demonstrate substantial equivalence to a predicate medical device.

59. The first components of the Zimmer M/L Taper® Hip System were cleared for sale in the United States according to Section 510(k) in October 2003.

FIRST CAUSE OF ACTION

Strict Products Liability - Unreasonably Dangerous Design

60. Plaintiff incorporates by reference paragraphs 1 through 59 of this Complaint, as if fully set forth herein and further allege as follows:

61. The Defendants had a duty to design and manufacture, and to place into the stream of commerce, distribute, market, promote and sell, the Zimmer M/L Taper® Hip System so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed, and sold.

62. On and prior to January 8, 2013, Defendants were engaged in the business of designing, manufacturing, marketing, distributing, and selling orthopedic hip implants and did design, manufacture, distribute, market and sell the Zimmer M/L Taper® Hip System that was implanted into the right hip of Plaintiff.

63. Defendants were engaged in selling, distributing, supplying and/or promoting the Zimmer M/L Taper® Hip System to Plaintiff and his implanting physician.

64. Defendants expected the Zimmer M/L Taper® Hip System they were selling, distributing, supplying, manufacturing and/or promoting to reach, and it did in fact reach, implanting physicians and consumers in the state of Tennessee including Plaintiff David Halstead and his implanting physician, without substantial change in the condition.

65. Plaintiff is in the class of persons that Defendants should reasonably foresee as being subject to the harm caused by the defectively designed Zimmer M/L Taper® Hip System, insofar as Plaintiff was the type of person for whom the hip implants were intended to be used.

66. At the time the Zimmer M/L Taper® Hip System left the Defendants' possession and the time the Zimmer M/L Taper® Hip System entered the stream of

commerce in the state of Tennessee, it was in an unreasonably dangerous or defective condition. These defects include, but are not limited to, the following:

a. the Zimmer M/L Taper® Hip System was not reasonably safe as intended to be used;

b. the Zimmer M/L Taper® Hip System had an inadequate design for the purpose of hip replacement;

c. the Zimmer M/L Taper® Hip System contained unreasonably dangerous design defects, including an inherently unstable and defective design paired with a Cobalt Chromium femoral head, which resulted in an unreasonably high metal wear debris, corrosion, fretting and probability of early failure;

d. the Zimmer M/L Taper® Hip Systems' unstable and defective design resulted in a hip prosthesis which had risks which exceeded the benefits of the medical device;

e. the Zimmer M/L Taper® Hip System was not appropriately or adequately tested before its distribution; and

f. the Zimmer M/L Taper® Hip System had an unreasonably high propensity for corrosion, fretting and fatigue under normal and expected use of the Zimmer M/L Taper® Hip System.

67. At the time of the Defendants' initial design and manufacture, and of all Defendants' marketing and sale of the Zimmer M/L Taper® Hip System, a feasible, alternative safer design for the Zimmer M/L Taper® Hip System was known and available, including, but not limited to, a design that utilized a ceramic femoral head and monoblock design. A ceramic head would reduce and/or eliminate metal debris and particles.

68. At the time of and subsequent to the Defendants' initial design and manufacture, marketing and sale of the Zimmer M/L Taper® Hip System, including prior

to the time of Plaintiff's hip implant surgery, Defendants had the ability to eliminate the unsafe character of the Zimmer M/L Taper® Hip System without impairing its usefulness.

69. Had the Defendants properly and adequately tested the Zimmer M/L Taper® Hip System, they would have discovered that the components, paired with a cobalt chromium femoral head, generated excessive metal wear caused by the surface contact of the metal articulating components resulting in pain, swelling, metallosis, tissue necrosis, bone necrosis, and a host of other maladies.

70. The Zimmer M/L Taper® Hip System devices, manufactured, supplied, distributed, marketed, promoted, and sold by Defendants, were, therefore, defective in design or formulation in that, when they left the hands of Defendants, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility the consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

71. At all times relevant hereto, Plaintiff and Plaintiff's healthcare providers used the Zimmer M/L Taper® Hip System for its intended or reasonably foreseeable purpose, and pursuant to instruction, guidance, education, and training provided by Defendants or agents of Defendants.

72. At all times relevant hereto, the Zimmer M/L Taper® Hip System was dangerous, unsafe, and defective in design including but not limited to its tendency to: (a) create dangerous and harmful metal debris in the patient's body; (b) cause pain; (c) inhibit mobility; and (d) require revision surgery with predictable cascading complications.

73. Defendants knew or should have known of the unreasonably dangerous and serious risks associated with the design of the Zimmer M/L Taper® Hip System.

74. Such risks were scientifically knowable to Defendants.

75. Defendants knew or should have known of the dangers.

76. Defendants either performed inadequate evaluation and testing; kept themselves willfully blind to the dangers; hid the dangers from physicians and patients, or some combination of the three.

77. As a direct, legal, and proximate result of Defendants' dangerous design, Plaintiff sustained injuries as set forth above.

78. Defendant's dangerous design and failure to adequately test contributed to cause the injuries suffered by Plaintiff.

79. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of the Zimmer M/L Taper® Hip System, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SECOND CAUSE OF ACTION

Strict Products Liability - Failure to Warn

80. Plaintiff incorporates by reference paragraphs 1 through 79 of this

Complaint, as if fully set forth herein and further allege as follows:

81. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Zimmer M/L Taper® Hip System, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, including the Plaintiff, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Zimmer M/L Taper® Hip System.

82. Defendants distributed and sold the Zimmer M/L Taper® Hip System devices in their original form of manufacture, which included the defects described herein.

83. The Zimmer M/L Taper® Hip System was defective and unreasonably dangerous when it left the possession of Defendants in that it contained an absence of warnings or limitations on when such device should be selected over safer alternatives.

84. The Zimmer M/L Taper® Hip System was defective and unreasonably dangerous when it left the possession of Defendants in that it contained an absence of warnings alerting the medical community and patients as to the dangerous risks associated with the Zimmer M/L Taper® Hip System when used for its intended and reasonably foreseeable purpose.

85. The risks associated with the Zimmer M/L Taper® Hip System when used for its intended and reasonably foreseeable purpose, include but are not limited to: (a) the creation of dangerous and harmful metal debris in the patient's body (b) pain; (c) mobility inhibition; and (d) likelihood of revision surgery with predictable cascading complications.

86. The Zimmer M/L Taper® Hip System was expected to and did reach Plaintiff and his implanting physician, in the state of Tennessee without substantial change or adjustment in its condition as manufactured and sold by Defendants.

87. The Zimmer M/L Taper® Hip System devices designed, developed, tested, manufactured, distributed, promoted, marketed and/or sold or otherwise placed into the stream of commerce by Defendants were in a dangerous and defective condition and posed a threat to any user or consumer of the Zimmer M/L Taper® Hip System devices.

88. At all times relevant hereto, Plaintiff was a person the Defendants should have considered to be subject to the harm caused by the defective nature of the Zimmer M/L Taper® Hip System devices.

89. Defendants' Zimmer M/L Taper® Hip System was implanted in Plaintiff and used in the manner for which it was intended.

90. This use has resulted in severe physical, financial, emotional and other injuries to Plaintiff.

91. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and his prescribing physician, of the true risks of the Zimmer M/L Taper® Hip System, including that the Zimmer M/L Taper® Hip System was susceptible to micromotion, fretting and corrosion at the junction, generating significant and toxic amounts of metal wear debris and corrosive byproducts in patients, causing severe pain and injury, and requiring further treatment, including revision surgeries and/or hip replacements.

92. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Zimmer M/L Taper® Hip System. Had they done so, proper Warnings would have been heeded and no health care professional, including Plaintiff's physician, would have used the Zimmer M/L Taper® Hip System, or no consumer, including Plaintiff, would have purchased and/or used the Zimmer M/L Taper® Hip System.

93. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Zimmer M/L Taper® Hip System.

94. The Zimmer M/L Taper® Hip System, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known that there was reasonable evidence of an association between the Zimmer M/L Taper® Hip System components and the development of corrosion, metal fatigue, failure, micromotion and/or release of significant amounts of metal debris and/or ions, causing serious injury and pain, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the Zimmer M/L Taper® Hip System.

95. The Zimmer M/L Taper® Hip System, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to

inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the Zimmer M/L Taper® Hip System resulting in revision surgery while knowing that a safer alternative design including, the use of a ceramic femoral head and monoblock stem components existed.

96. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

97. Plaintiff and his physician, used the Zimmer M/L Taper® Hip System for its intended purpose, i.e., hip replacement.

98. Plaintiff could not have discovered any defect in the Zimmer M/L Taper® Hip System through the exercise of due care.

99. Defendants, as designers, manufacturers, distributors, promoters, marketers and/ or sellers of medical devices are held to the level of knowledge of experts in their field.

100. Neither Plaintiff nor his implanting physician had substantially the same knowledge about the Zimmer M/L Taper® Hip System as Defendants.

101. Defendants reasonably should have known the device was unsuited for active individuals such as Plaintiff.

102. The warnings and instructions provided with the Zimmer M/L Taper® Hip System did not adequately educate and train medical providers as to the risk of side effects,

or the cost-benefit analysis necessary for justified use of this product versus safer alternative designs.

103. Defendants had a continuing duty to warn the medical community and public, including Plaintiff and Plaintiff's healthcare providers, of the potential risks and increased failure rates or propensity for failure associated with the Zimmer M/L Taper® Hip System.

104. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct as set forth herein, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses, and other damages, as set forth herein.

105. As a direct result of Defendants' failure to warn and/or inadequate warning and their other tortious conduct, Plaintiff has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages and economic loss in the future.

106. As a direct and proximate result of Defendants' failure to warn and/or inadequate warning and their other tortious conduct, as set forth herein, Plaintiff has suffered and will continue to suffer injuries, damages, and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

THIRD CAUSE OF ACTION

Strict Products Liability - Manufacturing Defect

107. Plaintiff incorporates by reference paragraphs 1 through 106 of this Complaint, as if fully set forth herein and further allege as follows:

108. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold the Zimmer M/L Taper® Hip System, in a condition which rendered it unreasonably dangerous due to its propensity to result in early failure of the device. The subject product was unreasonably dangerous in construction or composition.

109. The Zimmer M/L Taper® Hip System manufactured and/or supplied by Defendants was defective in manufacture, construction or composition in that, when it left the hands of Defendants, it deviated in a material way from Defendant's manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. Defendants knew or should have known that the Zimmer M/L Taper® Hip System could fail early in patients therefore giving rise to pain and suffering, debilitation and the need for revision surgeries to replace the device with the attendant risks of complications and death from such further surgeries, but Defendants continued to market the Zimmer M/L Taper® Hip System as a safe and effective hip replacement system.

110. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied, and introduced into the stream of commerce by Defendant, Plaintiff suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages, and economic loss in the future.

FOURTH CAUSE OF ACTION

Negligence

111. Plaintiff incorporates by reference paragraphs 1 through 110 of this Complaint, as if fully set forth herein and further allege as follows:

112. While the focus of Plaintiff's strict liability claims (Counts I-III) is on the condition of the product, the focus of Plaintiff's negligence claim is instead on Defendants' conduct.

113. Defendants had a duty to exercise reasonable care in the design, formulation, manufacture, testing, quality assurance, quality control, labeling, and/or warning of the Zimmer M/L Taper® Hip System, including a duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events.

114. Defendants failed to exercise ordinary care in the design, formulation, manufacture, testing, quality assurance, quality control, labeling, and warning of the Zimmer M/L Taper® Hip System devices in that they knew or should have known that these products caused significant bodily harm and were not safe for use by consumers.

115. Defendants failed to exercise ordinary care in the sale marketing, promotions, and distribution of the Zimmer M/L Taper® Hip System devices in that they knew or should have known that these products caused significant bodily harm and were not safe for use by consumers.

116. The Defendants failed to exercise ordinary care in testing the Zimmer M/L Taper® Hip System prior to marketing, sale, and distribution of the Zimmer M/L Taper® Hip System.

117. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of the Zimmer M/L Taper® Hip System, including a duty to ensure that the Zimmer M/L Taper® Hip System did not pose a significantly increased risk of bodily injury to its users.

118. Defendants had a duty to exercise reasonable care in the advertising and sale of the Zimmer M/L Taper® Hip System, including a duty to warn Plaintiff and other consumers, of the dangers associated with the Zimmer M/L Taper® Hip System that were known or should have been known to Defendants at the time of the sale of the Zimmer M/L Taper® Hip System to the Plaintiff.

119. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of the Zimmer M/L Taper® Hip System because Defendants knew or should have known that the Zimmer M/L Taper® Hip System had a propensity to cause serious injury, including adverse local tissue reaction, pseudotumor formation, metal debris, corrosion, metal ions, excessive wear, tissue necrosis, pain, swelling, metal ion release, loosening of the implants, bone loss, decreased range of motion, diminished mobility, and revision surgeries.

120. Defendants failed to exercise ordinary care in the labeling of the Zimmer M/L Taper® Hip System and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiff, regarding the risk of serious injury, including adverse local tissue reaction, pseudotumor formation, metal debris, corrosion, metal ions, excessive wear, tissue necrosis, pain, swelling, metal ion release,

loosening of the implants, bone loss, decreased range of motion, diminished mobility, and revision surgeries.

121. Defendants knew or should have known that Plaintiff could foreseeably suffer ordinary care as described above.

122. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances as follows:

(a.) Failing to use due care in the development, design, formulation, manufacturing, labeling, testing, assembly, marketing, advertising, promotion, inspection, sale and/or distribution of the Zimmer M/L Taper® Hip System, and/or to utilize and/or implement reasonably safe designs for them;

(b.) At all times relevant hereto, Defendants knew or should have known that the design of the Zimmer M/L Taper® Hip System was generating the potential for metal on metal problems, vulnerabilities, and injuries;

(c.) Defendants failed to perform sufficient clinical trials and other pre-marketing evaluations to determine risk and efficacy of the Zimmer M/L Taper® Hip System;

(d.) Such testing would have revealed the increased risk of failure and tendency to cause significant corrosion, metal wear debris, metal byproduct release, resulting in necrosis, pain, swelling, adverse local tissue reaction, trunnionosis, and/or metallosis;

(e.) A reasonable manufacturer under the same or similar circumstances would have conducted additional testing and evaluation of the Zimmer M/L Taper® Hip System before placing it into the stream of commerce;

(f.) A reasonable manufacturer under the same or similar circumstances would have conducted adequate testing of all junctions coupled with the cobalt-chromium femoral head and evaluation of the Zimmer M/L

Taper® Hip System before placing it into the stream of commerce;

(g.) A reasonable manufacturer under the same or similar circumstances would have required that significant information be provided to physicians regarding the risks associated with foreseeable metal on metal problems stemming from the design;

(h.) At all times relevant hereto, Defendants knew or should have known of the serious complications and high failure rate associated with the Zimmer M/L Taper® Hip System;

(i.) Failing to provide adequate and proper warnings to the public and to Plaintiff of the dangerous propensities of the Zimmer M/L Taper® Hip System when used in a reasonably foreseeable manner;

(j.) Failed to conduct adequate post marketing surveillance;

(k.) Failing to design, formulate, manufacture and

incorporate or to reformulate the Zimmer M/L Taper® Hip System with reasonable safeguards and protections against the type of injury and damage suffered by Plaintiff when used in a reasonably foreseeable manner;

(l.) Failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Zimmer M/L Taper® Hip System in accordance with good design practices;

(m.) Failing to notify and warn the public including Plaintiff, of reported incidents involving injury, etc., and the negative health effects attendant to the use of the Zimmer M/L Taper® Hip System, thus misrepresenting the safety of the product;

(n.) Failing to make timely and adequate corrections to the manufacture, design and formulation of the Zimmer M/L Taper® Hip System so as to prevent and/or minimize the problems suffered by the Zimmer M/L Taper® Hip System use;

(o.) Despite its knowledge of these risks, Defendants continued to promote and market the device; and,

(p.) Being otherwise careless, reckless and negligent.

123. Despite knowing or having reason to know of the risks, Defendants did not (1) perform additional testing, (2) investigate the risks, (3) suspend sales or distribution, (4) warn physicians or patients of the propensity for the Zimmer M/L Taper® Hip System to cause or create significant corrosion, metal wear debris, metal byproduct release, resulting in necrosis, pain, swelling, dislocation, osteolysis, pseudotumor formation, adverse local tissue reaction, trunnionosis, metallosis, and/or need for early surgical revisions.

124. As a direct and proximate result of Defendants acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, labeling, warnings and distribution of the Zimmer M/L Taper® Hip System, Plaintiff was implanted with the Zimmer M/L Taper® Hip System and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

FIFTH CAUSE OF ACTION

Negligent Misrepresentation

125. Plaintiff incorporates by reference paragraphs 1 through 124 of this

Complaint, as if fully set forth herein and further allege as follows:

126. Prior to the Plaintiff receiving the Zimmer M/L Taper® Hip System, Defendants misrepresented that the Zimmer M/L Taper® Hip System was a safe and effective total hip replacement system.

127. In the exercise of reasonable care, Defendants should have known that the Zimmer M/L Taper® Hip System device failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification, yet they negligently misrepresented to Plaintiff and/or his physician that their device was safe and met all applicable design and manufacturing requirements.

128. Defendants failed to disclose material facts regarding the safety and efficacy of the Zimmer M/L Taper® Hip System utilizing a CoCr femoral head, including information regarding increased risk of failure, harmful side-effects, increased risk of revision surgeries, and lack of adequate testing.

129. Defendants had a duty to provide Plaintiff, physicians and other consumers with true and accurate information and warnings of any known risks and harmful side effects of the medical devices they marketed, distributed, and sold.

130. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures associated with the Zimmer M/L Taper® Hip System, that their representations regarding the Zimmer M/L Taper® Hip System were false, and that they had a duty to disclose the dangers associated with the devices.

131. Plaintiff and his physician reasonably relied, to Plaintiff's detriment, upon Defendants' misrepresentations and material omissions in their marketing, advertisements, and promotions concerning the quality and safety of the Zimmer M/L Taper® Hip System. Plaintiff and his physicians reasonably relied upon Defendants' representations that the Zimmer M/L Taper® Hip System was of high quality and safe for implantation into his body.

132. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including the Plaintiff, and the medical community to act in reliance by purchasing the Zimmer M/L Taper® Hip System with a CoCr femoral head.

133. Defendants' representations and nondisclosures regarding the safety and efficacy of the Zimmer M/L Taper® Hip System was the direct and proximate cause of Plaintiff's injuries.

134. Defendant's conduct, as described above, was reckless and imprudent. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

135. Plaintiff and/or his physician justifiably relied to their detriment upon Defendants' misrepresentations and omissions in their marketing, advertisements, promotions, and labeling concerning these products.

136. Plaintiff and/or his physician justifiably relied upon Defendants' representations that the Zimmer M/L Taper® Hip System devices were safe for use in persons such as Plaintiff.

137. As a direct and proximate result of Defendants' negligent misrepresentations and/or omissions regarding the Zimmer M/L Taper® Hip System devices, Plaintiff used the devices and has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

138. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff has suffered and will continue to suffer injuries, damages, and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

SIXTH CAUSE OF ACTION

Breach of Express Warranty

139. Plaintiff incorporates by reference paragraphs 1 through 138 of this Complaint, as if fully set forth herein and further allege as follows:

140. Defendants advertised, labeled, marketed, and promoted the Zimmer M/L Taper® Hip System, representing the quality to health care professionals, the FDA, Plaintiff, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Zimmer M/L Taper® Hip System would conform to the representations. More specifically, Defendants represented that the Zimmer M/L Taper® Hip System was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat Plaintiff's condition.

141. The representations, as set forth above, contained, or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

142. The Zimmer M/L Taper® Hip System did not conform to the representations made by Defendants in that the Zimmer M/L Taper® Hip System was not safe and effective, was not safe and effective for use by individuals such as Plaintiff, and/or was not safe and effective to treat in individuals, such as Plaintiff.

143. At all relevant times, Plaintiff used the Zimmer M/L Taper® Hip System for the purpose and in the manner intended by Defendants.

144. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

145. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

146. Within a reasonable time after Plaintiff knew or should have known of the failure of his Zimmer M/L Taper® Hip System components, Plaintiff gave notice to Zimmer of such failure.

147. Zimmer breached the express warranty it provided with the devices.

148. As a direct and proximate result of Defendant's acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of the Zimmer M/L Taper® Hip System, Plaintiff was implanted with the

Zimmer M/L Taper® Hip System and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION

Breach of Implied Warranty

149. Plaintiff incorporates by reference paragraphs 1 through 148 of this Complaint, as if fully set forth herein and further allege as follows:

150. The Zimmer M/L Taper® Hip System was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual, and reasonably foreseeable manner. Nor was the Zimmer M/L Taper® Hip System minimally safe for its expected purpose.

151. At all relevant times, Plaintiff used the Zimmer M/L Taper® Hip System for the purpose and in the manner intended by Defendants.

152. Plaintiff and Plaintiff's physicians, by use of reasonable care could not have discovered the breached warranty and realized its danger.

153. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

154. Zimmer impliedly warranted that the Zimmer M/L Taper® Hip System and its component parts were merchantable and fit for the ordinary and intended purposes for which hip systems are used.

155. Plaintiff was a foreseeable user of the Zimmer M/L Taper® Hip System.

156. Plaintiff's surgeon, as purchasing agent, purchased the Zimmer M/L Taper® Hip System for Plaintiff from Zimmer.

157. At all times relevant to this Complaint, Plaintiff was and is in privity with Zimmer.

158. Plaintiff used the products for their ordinary and intended purpose.

159. The Zimmer M/L Taper® Hip System failed while being used for its ordinary and intended purpose.

160. As a direct and proximate result of Zimmer's breach of implied warranty of merchantability, Plaintiff suffered injuries as described specifically above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff David Halstead prays for judgment and an award of damages against Defendants, as follows:

(a) for special damages, to include past and future medical and incidental expenses, according to proof;

(b) for past and future loss of earnings and/or earning capacity, according to proof;

(c) for past and future general damages, to include pain and suffering, emotional distress and mental anguish, according to proof;

(d) for pre-judgment and post-judgment interest;

(e) for the costs of this action;

(f) granting any and all such other and further legal and equitable relief as the Court deems necessary, just and proper; and,

(g) awarding treble and/or punitive damages to Plaintiff.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury to the full extent permitted by law.

Dated: December 20, 2021

Respectfully Submitted,

/s/ Ashley L. Upkins, Esq. (#033598)
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